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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,324	04/25/2001	Jeffrey M. Staub	15869/01	8784

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,324

Applicant(s)

STAUB ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on with the application is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group III (claims 13-22) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that that it would not be an undue burden to search all the claims. This is not found persuasive because the different methods require different searches and thus examination of all the groups would be an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 are withdrawn from consideration as being drawn to non-elected inventions.

2. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

3. Reference B1 in the information disclosure statement filed 25 February, 2002, fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of this patent not in the English language. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of this item of information or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Objections

4. Claims 16 and 18 are objected to because of the following informalities:

In claim 16, "herbicides" should be replaced with --a herbicide--, and --a-- should be inserted before each of "protease" and "nuclease".

In claim 18, "comprise" should be plural.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of transforming plastids with a construct comprising a plastid promoter, a nucleic acid comprising the EPSPS coding sequence, and a transcriptional termination region, wherein the transformed plant cell is first selected on low concentration of glyphosate, then after a period of time is selected on a higher concentration, does not reasonably provide enablement for a method of transforming plastids with a construct comprising a plastid promoter, any nucleic acid that encodes a protein that provides tolerance to a plastid lethal compound, and a transcriptional termination region, wherein the transformed plant cell is first selected on low concentration of any plastid lethal compound, then after a period of time is selected on higher concentrations of any plastid lethal compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Art Unit: 1638

The claims are broadly drawn to a method of transforming plastids with a construct comprising a plastid promoter, any nucleic acid that encodes a protein that provides tolerance to a plastid lethal compound, and a transcriptional termination region, wherein the transformed plant cell is first selected on low concentration of any plastid lethal compound, then after a period of time is selected on higher concentrations of any plastid lethal compound.

The instant specification, however, only provides guidance for electron microscopic analysis of tobacco leaves exposed to glyphosate (example 1); construction of plastid transformation vectors comprising expression cassette comprising the *Prrn* promoter, a sequence encoding the first 14 amino acids of GFP or *atpB* fused to EPSPS, and the *rps16* termination sequence, wherein the expression cassette is flanked by either the tobacco *trnV/rps12/rps7* repeat region or the tobacco *rbcL/accD* sequences, or with a vector comprising an expression cassette comprising the *Prrn* promoter, *bar*, and the *rpsL* termination sequence, wherein the expression cassette is flanked by the tobacco *trnV/rps12/rps7* repeat region (example 2); transformation of tobacco plastids with a vector comprising an expression cassette comprising the *aadA* selectable marker and one of the EPSPS vectors above, wherein selection first occurs on spectinomycin, then after 4-8 weeks transformants are transferred to glyphosate to produce plants that have the EPSPS vector but not the *aadA* vector and those that have both, as determined by Southern blot hybridization (example 3); transformation of tobacco plastids with a vector comprising an expression cassette comprising the *aadA* selectable marker and the *bar* vector above, wherein selection first occurs on spectinomycin, then after 4-8 weeks transformants are transferred to phosphinothricin to produce plants that have the *bar* vector but not the *aadA* vector and those that have both, as determined by Southern blot hybridization (example 3); and transformation of

tobacco plastids with a vector encoding both EPSPS and *aadA*, wherein selection first occurs on 10 μ M glyphosate, then after 3 weeks transformants are transferred to 100 μ M glyphosate (example 4). The specification also teaches that direct selection on phosphinothricin does not work (pg 30, lines 16-20).

The instant specification fails to provide guidance for a method of transforming plastids with a construct comprising a plastid promoter, a nucleic acid that encodes a protein that provides tolerance to a plastid lethal compound, and a transcriptional termination region, wherein the transformed plant cell is first selected on low concentration of a plastid lethal compound, then after a period of time is selected on higher concentrations of a plastid lethal compound and wherein the nucleic acid encodes any herbicide tolerance gene or encodes an inhibitor of plastid metabolic pathways, protease, or nuclease or a protein that provides tolerance to those things, or wherein the lethal compound is any herbicide a protease a nuclease or a plastid metabolic pathway inhibitor.

Both the instant specification (pg 30, lines 16-20) and Lutz et al (2001, Plant Physiol. 125:1585-1590, see pg 1587, left column, paragraph 2) teach that direct selection on phosphinothricin does not work.

As the specification does not describe the transformation of any plant with a gene encoding any herbicide tolerance gene or encodes an inhibitor of plastid metabolic pathways, protease, or nuclease or a protein that provides tolerance to those things, undue trial and error experimentation would be required to screen through the plastid transformation vectors and plastid lethal compounds, as encompassed by the methods of the claims, to identify those that produce plants with transformed plastids, if such plants are even obtainable.

Art Unit: 1638

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 13 lacks antecedent basis for the limitation "said plant cell" in step (b).

It is not clear in claim 13 if the plastid lethal compound under in step (c) and referred to again in the last line of the claim is the same plastid lethal compound used in step (b). Additionally, it is not clear if the nucleic acid sequence encoding a protein providing tolerance to a plastid lethal compound (step a) provides its tolerance to both of the plastid lethal compounds used in steps (b) and (c), to only one of them, or to neither of them.

Claims 14 and 15 are indefinite in their recitation of "encodes for proteins..." The use of the plural for proteins implies that the nucleic acid sequence encodes more than one protein. However, parent claim 13, in part (a) states that the nucleic acid sequence encodes a protein.

Claim 14 is indefinite in its recitation of "said nucleic acid sequence encodes for proteins selected from the group consisting of genes ... herbicides". Genes are not proteins.

Art Unit: 1638

In claim 14 it is unclear if proteins are inhibitors of plastid metabolic pathways, proteases or nucleases themselves or if they provide tolerance to inhibitors of plastid metabolic pathways, proteases or nucleases.

Claim 18 is indefinite in its recitation of "regions of plastid homology". It is not clear to which plastid the regions are homologous, nor is the level of homology clear.

9. Claims 13-22 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims are drawn to a method for obtaining a transplastomic plant. However, step (c) of claim 13, upon which the other claims depend, involves selection of plant cells. The omitted steps are those involved in regeneration of the plant cells into a plant.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 13-14 and 16-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Blowers et al (WO 99/05265).

Blowers et al teach a method of transforming tobacco plastids with a construct comprising the plastid 16S rDNA promoter, a nucleic acid, *hph*, which encodes a protein, hygromycin phosphotransferase, which provides tolerance to the plastid lethal compound glyphosate, the *psbA* transcriptional termination region and regions of homology to the petunia chloroplast genome (the ORF70B and the *trnV*-16S rDNA-*trnI* genes; pg 49-50), wherein the transformed plant cell is first selected on low concentration of glyphosate, then after 5-6 weeks is selected on higher concentrations (pg 51, paragraph 2; pg 69, paragraph 2). 5-6 weeks is less than "about 3" weeks.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 13-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blowers et al (WO 99/05265) in view of Daniell et al (1998, Nature Biotechnol. 16:345-348).

The claims are drawn to a method of transforming plastids with a vector comprising a plastid promoter, a nucleic acid that encodes EPSPS, and a transcriptional termination region, wherein the transformed plant cell is first selected on low concentration of glyphosate, then after less than 8 weeks is selected on higher concentrations of glyphosate.

The teachings of Blowers et al are discussed above. Blowers et al do not disclose plastid transformation vectors encoding EPSPS.

Daniell et al teach that plants whose plastids are transformed with a vector comprising an EPSPS expression cassette are resistant to even high levels of glyphosate (pg 348, left column, paragraph 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of transforming plastids, wherein the transformed plant cell is first selected on low concentration of glyphosate, then is selected on higher concentrations of glyphosate. as taught by Blowers et al, to use the EPSPS coding sequence in the vector as described in Daniell et al. One of ordinary skill in the art would have been motivated to do so because substitution of one gene that confers resistance to glyphosate for another is an obvious design choice.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.
October 16, 2002



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